

**AMENDMENTS TO THE DRAWINGS**

The attached sheet of drawings includes changes to FIGS. 7A-7C and the addition of new FIG. 7D.

Please amend FIGS. 7A-7C to include cross-hatching to more clearly show the components as in FIGS. 1-3.

Please add FIG. 7D to show an O-ring and a wall defining the proximal portion of the passageway proximal of the O-ring being tapered. Support for FIG. 7D can be found in the originally filed application at, for example, paragraphs [0042] and [0047].

Attachments:      Replacement sheet 5/5  
                         Annotated sheet 5/5 showing changes

**REMARKS**

The Office Action mailed May 30, 2008 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 30-39 are pending in this application. Claims 34-36 are withdrawn from further consideration as being drawn to a non-elected Species. No amendments to the claims are made herein. The specification and drawings are amended herein. Applicant submits that no new matter has been introduced.

**Drawings**

The drawings stand objected to under 37 C.F.R. § 1.83(a). The Office Action alleges that FIGS. 7A-7C do not show the features recited in the claims. In particular, the Office Action alleges that the valve features of claim 30, the O-ring and tapered passageway of claim 33, and the compression ring of claim 39 are not shown in the drawings. In response, Applicant has amended FIGS. 7A-7C to show the cross-hatching present in FIGS. 1-3 to thereby more clearly indicate the valve features of claim 30. Further, Applicant submits herewith new FIG. 7D to show the O-ring/compression ring 510 and the tapered passageway 512 of claims 33 and 39. The specification is amended herein, accordingly. Thus, in view of the above, Applicant has addressed the objections in the Office Action and therefore requests withdrawal of the objection under 37 C.F.R. § 1.83(a).

**Claim Rejections - 35 U.S.C. § 112**

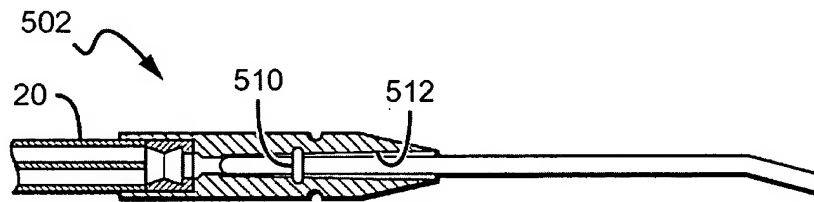
Claims 30 and 37 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection.

The Office Action alleges that claim 30 is "misdescriptive" due to the allegation that the recitation of "a proximal portion of the passage way including an engagement feature configured to connect an end of an instrument to the connector" does not match with the drawings.

First, repeating Applicant's assertion in the previous response (not commented on by the Examiner), the second paragraph of 35 U.S.C. § 112 is directed to requirements for *claims* (see MPEP § 2171). Thus, "the content of applicant's specification is not used as evidence that the

scope of the claims is inconsistent with the subject matter which applicants regard as their invention.” (MPEP § 2172, p. 2100-217, Rev. 6, Sept. 2007). Again, Applicant submits that there is nothing indefinite in claim 30 as the language therein is precise, clear, correct and unambiguous.

Second, the Examiner is incorrect in asserting that the claimed language does not match with the drawings. As the drawing below clearly shows, there is no inconsistency between the claim and specification disclosure pursuant to MPEP § 2173.03. In particular, the Examiner is conflating distal and proximal as shown below, and has mistaken tunneler 50 for catheter 20. Further, although believed by Applicant to be unnecessary, in the interest of compact prosecution, Applicant has included herein new FIG. 7D to show the features clearly described (*see* paragraph [0047], a section of which is reproduced below) in the instant specification with respect to elected species 7A-7C.



**FIG. 7D**

After the catheter is placed and the tunneler is positioned in the subcutaneous tunnel, the proximal end of the connector housing 502 is slid over the tip of the tunneler 50. A compression ring, such as O-ring 510, grips the tunneler tip, allowing the catheter to be withdrawn through the subcutaneous tunnel by pulling the connector 502 through to an exit site. As described above, a wall 512 defining a portion of the passageway proximal the O-ring may be tapered.

Thus, Applicant submits that claim 30 is accurately descriptive and is consistent with the specification as originally filed and respectfully requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

### **Claim Rejections - 35 U.S.C. § 102**

Claims 30-31, 33, and 37-39 stand rejected under 35 U.S.C. § 102(e) as being anticipated by US 2004/0193119 to Canaud et al. (hereinafter, "Canaud"). Claims 30-33 and 37-39 stand rejected under 35 U.S.C. § 102(e) as being anticipated by USPN 5,935,112 to Stevens et al. (hereinafter, "Stevens"). Applicant respectfully traverses these rejections.

#### Canaud

Independent claim 30 recites, *inter alia*, "a distal portion of the passageway including a valve having a closed proximal end with a slit and an open distal end." Independent claim 37 similarly recites, *inter alia*, "a distal portion of a connector housing lumen including a valve having a closed proximal end with a slit and an open distal end."

In the Response to Arguments section of the Office Action, the Examiner argues that the phrase in Canaud, "although those skilled in the art will recognize that other types of valves may be used" is sufficient for the disclosure of the claimed feature of a "valve having a closed proximal end with a slit and an open distal end." The Examiner justifies this position by stating that it follows that the Canaud valve "inherently/must have a slit/small hole for fluid flow" and "can be used with other types of valve[s]." Applicant disagrees with the Examiner's position.

By invoking the doctrine of inherency, the Examiner has taken the position that the subject matter of a *particular type and configuration of valve* necessarily/inevitably flows from the comment in Canaud that "other types of valves may be used." (*see* MPEP § 2112). Applicant notes that inherency is not established by mere probabilities or even possibilities. (*see* MPEP § 2112). Essentially, the Examiner is asserting that "other types of valves may be used" means that any and all valves ever contemplated in the past or future are anticipated as inherent by disclosure in Canaud of a "bidirectional valve or a duckbill valve." Applicant submits that this position is untenable.

Importantly, Applicant is claiming a particular type of valve, namely a “valve having a closed proximal end with a slit and an open distal end,” at least in part because Applicant has discovered particular advantages to overcome recognized issues with prior art valves, such as, for example, those discussed in the application as originally filed at paragraph [0010]. By utilizing the claimed slit valve, a sealing function is provided that distinguishes over other valves, such as those specifically disclosed in Canaud. Further, the slit valve permits threading the catheter over an inserted guidewire with the adaptor attached (*see* paragraph [0039] of the instant application), which is not a possibility mentioned by Canaud.

Accordingly, in view of the above, Applicants submit that independent claims 30 and 37, and claims 31, 33, 38 and 39 depending therefrom, are not anticipated by Canaud at least because Canaud does not show or describe, either expressly or inherently, “a distal portion of the passageway including a valve having a closed proximal end with a slit and an open distal end” (claim 30), or “a distal portion of a connector housing lumen including a valve having a closed proximal end with a slit and an open distal end” (claim 37). Therefore, Canaud does not show each and every element as set forth in the claims.

Further, dependent claim 33 recites *inter alia*, “a wall defining the proximal portion of the passageway proximal of the O-ring is tapered.” The Office Action does not state where in Canaud support for this feature can be found. In fact, Canaud actually teaches away from such a configuration by stating that “the passageway 206 has a generally constant diameter between the distal end 202 and the proximal end 204 to promote laminar fluid flow through the passageway 206.” Canaud, paragraph [0039]. Thus, in addition to the deficiency of Canaud discussed above, Applicant submits that the claimed feature of dependent claim 33 is also not shown or described by Canaud.

With further respect to independent claim 37, the Office Action alleges that the Canaud adaptor 420 can be a syringe adaptor. However, while Canaud shows and describes connecting a syringe to luer connector 420 on port 400 (Canaud, paragraph [0066]), there is not showing or description of a connector housing including a *tapered proximal end* with a separate syringe adaptor

including a distal end *configured to slide over the tapered proximal end of the connector housing*. In other words, even assuming *arguendo* that the Canaud port could be considered the claimed connector, there is no showing of a tapered end and there is no additional adaptor shown to act as the claimed syringe adaptor. Alternatively, if the port 400 is considered to be the claimed syringe adaptor, there is no showing of a connector over which the syringe adaptor is configured to *slide*.

Further still, claim 37 requires that the connector have an opening *configured to receive a proximal end of a catheter*. The Office Action alleges that the claimed connector is shown by component 200, 270 (FIGS. 2-3) or 700 (FIGS. 19-20). However, assuming *arguendo* that the adaptor 200, 270 or port assembly 700 could be considered a connector as claimed, there is no showing or description of a distal end with an opening configured to receive a proximal end of a catheter, as claimed. To the contrary, the Canaud components are configured for insertion into a proximal end of a catheter, as the following passages from Canaud expressly state (underlining added for emphasis):

Referring to FIGS. 9 and 10, the distal end 202 of the adapter 200 is inserted into the proximal end 502 of a lumen 504 of a catheter 500. The distal end 202 of the adapter 200 is inserted sufficiently into the lumen 504 such that the catheter 500 extends over the retaining nub 212.

Canaud, paragraph [0058]

The distal portion 702 of port assembly 700 is inserted sufficiently into the lumen such that the catheter extends over the barbs 710

Canaud, paragraph [0072]

Thus, Canaud does not show or describe the feature of a connector with a distal end having an opening *that is capable* of receiving a proximal end of a catheter, because by definition, if a distal end of the adaptor is to be *inserted into* the catheter lumen, it can't possibly be capable of receiving within its opening that same catheter.

Accordingly, in view of the above, Applicant respectfully requests favorable reconsideration and withdrawal of the rejection of claims 30-31, 33, and 37-39 under 35 U.S.C. § 102 as anticipated by Canaud.

Stevens

Independent claim 30 recites, *inter alia*, “a proximal portion of the passageway including an engagement feature configured to connect an end of an instrument to the connector.” The Office Action alleges that Stevens discloses a connector as claimed, but does not state with specificity where in Stevens there is shown or described a connector including a passageway including an engagement feature in a proximal portion thereof. As argued by Applicant in the previous response, the Office Action cites only to elongated housing 42 as anticipatory disclosure of the claimed connector, but not to any feature that allegedly shows an engagement feature in a proximal portion of the passageway. As previously pointed out by Applicant, FIG. 2 of Stevens shows an exploded cross-sectional view of the housing 42. However, even if the alleged “proximal portion of the passageway” was identified as bore 86 or compression chamber 88, neither bore 86 or chamber 88 are shown or described as including “an engagement feature configured to connect an end of an instrument to the connector,” as claimed.

In the Remarks to Arguments section of the Office Action, the Examiner does not address this deficiency of Stevens. Accordingly, until the Office cites with specificity to a drawing or passage in Stevens that allegedly discloses this claimed feature, Applicant maintains that independent claim 30, and claims 32-33 depending therefrom, are not anticipated by Stevens. Therefore, Applicant respectfully requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 102.

Independent claim 37 recites, *inter alia*, “a syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing and a proximal opening configured to receive a male luer portion of the syringe.” The Office Action alleges that Stevens discloses “a syringe adaptor 46” (Office Action, p. 5). However, with reference to FIG. 2, Stevens identifies reference numeral 46 as a “rotatable end cap” with a proximal end 182 and a distal end

184, the distal end including on an interior surface engagement second threads 202 “for rotational, threaded engagement with first engagement threads 120 on proximal end 84 of housing 42.” (Stevens, col. 11, ll. 40-49). The proximal end of the rotatable end cap includes an interior surface 218 that expands radially outward “to form an enlarged retaining mouth 222.”

Thus, assuming *arguendo* that the rotatable end cap 46 of Stevens is a syringe adaptor as alleged, then the claimed connector must be viewed by the Examiner as housing 42, as it is the engagement threads 120 of housing 42 over which the threaded end cap 46 is rotated. However, the proximal end of the housing 42 is not shown or described to include *a tapered proximal end* as claimed. In the Remarks to Arguments section of the Office Action, the Examiner argues that the recitation of the syringe adaptor “configured to slide over the tapered proximal end of the connector” is merely intended use. However, the Examiner does not point out where, in Stevens, there is disclosure of a “connector housing including a tapered proximal end” as claimed in independent claim 37. Thus, Stevens does not show or describe each and every limitation as set forth in independent claim 37 as required under 35 U.S.C. § 102. Therefore, Applicant submits that independent claim 37, and claims 38-39 depending therefrom, are not anticipated by Stevens and respectfully requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 102.

### **Claim Rejections - 35 U.S.C. § 103**

Claim 32 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Canaud or Stevens. Applicant respectfully traverses this rejection.

In view of the above, without conceding the propriety of the rejection, Applicant submits that claim 32 depends from patentable independent claim 30 and is therefore patentable. Accordingly, Applicant respectfully requests favorable reconsideration and withdrawal of this rejection under 35 U.S. C. § 103.



### Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicant of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 50-2191 referencing docket no. 1016720019P. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 29, 2008

Respectfully submitted,

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ANNOTATED SHEET SHOWING CHANGES

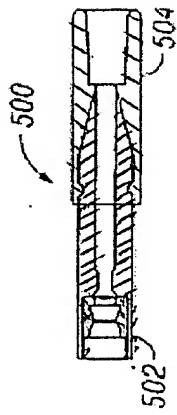


FIG. 7A

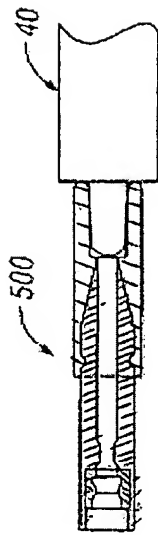


FIG. 7B

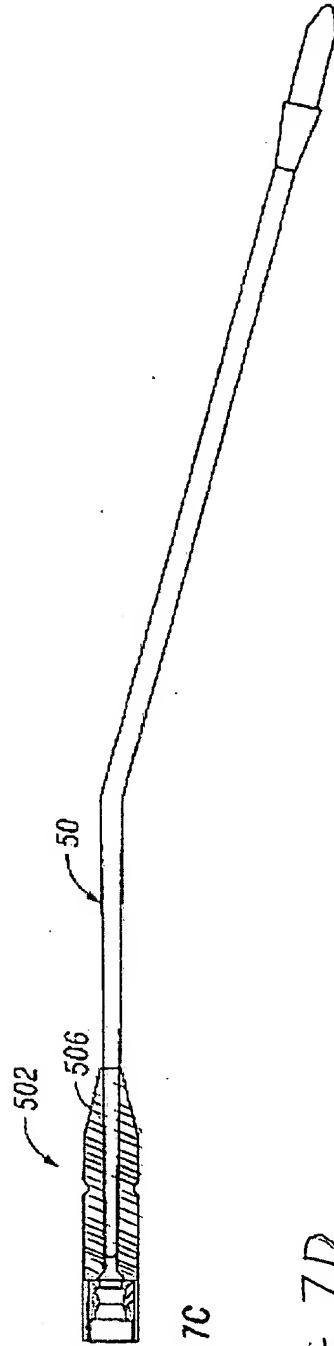


FIG. 7C

FIG. 7D